

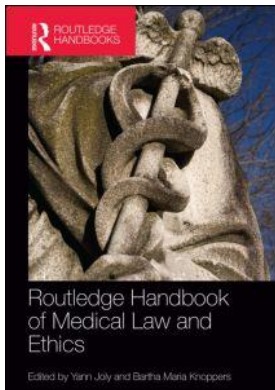
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15.1 Introduction

The international healthcare market is developing rapidly and different healthcare systems are converging. Privately financed healthcare systems pay more attention to justice and equal access. Publicly financed healthcare systems are introducing cost-efficiency techniques privately financed healthcare systems used in the past. At the same time, healthcare actors are increasingly leaving their own national borders to participate in cross-border care. With cross-border activities in healthcare growing more frequent, *patients* tend to be treated in other countries to avoid long waiting lists. Alongside this, *consumers/patients* use the Internet to search for medical information or to order medicinal products from pharmacies located in other countries. Moreover, *doctors* demand more and varied telematic information from their colleagues than previously. *Healthcare professionals, hospitals and laboratories* increasingly rely on information and communication technology (ICT) applications to disseminate health data for treatment and other purposes throughout several countries. Many healthcare institutions (like national health insurers, hospitals, laboratories, etc.) are becoming more involved on the international healthcare stage and communicate health data between member states for treatment and other purposes. Against the backdrop of these developments, e-health plays an important role in both developed and developing countries (World Health Organization (WHO) 2012a: 7).¹ It is clear that e-health in itself has an impact on healthcare systems and healthcare actors. Given the supportive role of ICT-development in wider systems, such as social welfare systems, it is reasonable to believe it will also influence healthcare systems.

E-health is popularly defined as 'health services and information delivered through the Internet and related technologies' (European Group on Ethics in Science and New Technologies to the European Commission 2012: 33; Kelly 2011: 27). E-health describes the application of information and communication technologies across the whole range of functions that affect the healthcare sector. According to the European Commission, e-health comprises the following

¹ However, the implementation of e-health services proves to be more difficult in low-income countries than in higher-income countries and emerging economies (WHO 2012b: 53).

four interrelated categories of applications: (a) clinical information systems; (b) telemedicine² and home care, personalised health systems and services for remote patient monitoring, teleconsultation, telecare, telemedicine and teleradiology; (c) integrated regional/national health information networks, distributed electronic health record systems and associated services such as e-prescriptions or e-referrals; and (d) secondary usage of non-clinical systems (such as specialised systems for researchers or support systems such as billing systems) (eHealth Taskforce 2007: 10). E-health is continuously changing as the emergence of mobile health – defined as ‘the use of mobile communication and devices for providing healthcare services or achieving health outcomes’ (PricewaterhouseCoopers (PwC) and Groupe Speciale Mobile Association (GSMA) 2012: 14) – demonstrates. Therefore an ethical and legal framework for e-health must also be broad enough to encompass current as well as future solutions (PwC and GSMA 2012: 14).

E-health can be used in a beneficial way when addressing key challenges our health systems face (e.g. demographic change, reduced human resources) (Stroetmann *et al.* 2012: 3). According to the European Group on Ethics in Science and New Technologies to the European Commission:

reductions in health budgets and competition for limited resources require enhanced efficiency and efficiency of health services. For meeting all of these challenges, adequate information and knowledge are required and e-Health applications offer the prospect of acquiring information which is accurate, reliable and timely.

(2012: 33)

Thus e-health is considered an important tool in establishing efficient healthcare delivery around the world (WHO 2012a: 12). In addition, the development, adoption and implementation of a broad range of e-health applications – such as electronic health records, health information websites, e-prescribing, home health monitoring and tele-health – has the potential to enhance quality of care. It also promises improved access to health treatment and advice, empowering patients to make informed healthcare decisions (European Group on Ethics in Science and New Technologies to the European Commission 2012: 33).

In this chapter, we provide an overview of international documents related to e-health. It will become obvious that it takes time to provide a framework that encompasses all of the issues related to e-health. Moreover, we are of the opinion that there are still several issues related to e-health that need specific attention when creating rules regarding its use. These issues are described in [section 15.3](#).

15.2 The impact of international documents for e-health

15.2.1 World Health Organization

At the international level, e-health is receiving a great deal of attention from the WHO. In 2005, the WHO launched the Global Observatory for eHealth (GOe), an initiative dedicated to the study of e-health, its evolution and its impact on health in countries. So far, the WHO has adopted three e-health resolutions. In the most recent, the WHO requests the Director-General,

² Telemedicine is defined by the European Commission in its *Communication on Telemedicine for the Benefit of Patients, Healthcare Systems and Society* as ‘(t)he provision of health care services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients’ (2008: 3).

within existing resources ‘to provide support to Member States, as appropriate, in their promotion of the full implementation of e-health and health data standard in all e-health initiatives’ (World Health Assembly 2013:), among other things. In addition to these specific resolutions, the WHO also enacted a declaration on the promotion of patients’ rights in Europe in 1994. Particularly, the principles regarding the right to access, correction, completion, deletion, clarification and/or updating of medical data and the right to informed consent are important (WHO 1994: 11–12). When processing health data using ICT, one should take into account patient privacy protections outlined in article 12 of the *Universal Declaration of Human Rights* 1948. This article states that ‘no one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks’ (*Universal Declaration of Human Rights*, article 12).

In support of e-health policy and strategic development, the WHO and the International Telecommunication Union (ITU) will soon launch a National e-health Roadmap Development Toolkit to support member states with the development of their own comprehensive e-health strategies (WHO 2011: 77). The WHO also announced that it will support the use of mobile health in member states to maximise its impact (WHO 2011: 3).

15.2.2 Council of Europe

Article 8 of the *European Convention on Human Rights* 1950 is important to developing an e-health infrastructure since it provides a general right to privacy protection.³ Relatedly, the *Convention on Human Rights and Biomedicine* 1997 contains specific rights that are significant in an e-health environment, such as the right to informed consent, the right to private life in relation to information about his or her health, and the right to any information collected about his or her health. For the protection of medical data in particular, the Council of Europe issued *Recommendation No. R(97)5 on the Protection of Medical Data* (1997).

15.2.3 European Union⁴

E-health has likewise received recognition at the EU level. Despite excluding health services from *Directive 2006/123/EC on Services in the Internal Market* 2006, it is clear the Commission has enacted effective rules governing healthcare. In turn, these rules have an important impact on healthcare systems, including the creation of an EU legal framework for e-health. The subsequent section first describes European policy initiatives on e-health, and gives an overview of legal documents related to its nature and implementation.

15.2.3.1 Policy of the Commission Regarding E-Health

The Commission is aware that e-health and/or telemedicine may contribute to delivering better quality of care and to better patient involvement in the management and follow-up of their health

³ Article 8 states: ‘1. Everyone has the right to respect for his private and family life, his home and his correspondence; 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others’ (*European Convention on Human Rights*).

⁴ This part is based on ‘The EU legal framework on e-health’, by S. Callens (2010).

condition(s) (European Commission 2007: 5). Within two decades, the Commission has invested 1 billion Euros in funding over 450 projects (European Group on Ethics in Science and New Technologies to the European Commission 2012: 33)⁵ and several research programmes related to e-health.⁶ Moreover, the Commission established an *Action Plan* for a European E-health Area in 2004 (European Commission 2004). In the *Action Plan*, health and healthcare formed a key part of the Commission's vision for an information society. It imagined a new generation of computerised clinical systems, advanced telemedicine services and health network applications to improve health, to provide continuity of care and to allow citizens to be more involved in and assume greater responsibility for their own health. The Commission believed that e-health would be an instrument for restructured, citizen-centred healthcare systems, while respecting the diversity of Europe's multicultural, multilingual healthcare traditions in the process (European Commission 2004: 4).

The 2004–2012 e-health action plan increased awareness among member states regarding the importance of making e-health an integral part of their health systems. Today, every EU member state has an e-health strategy in place and is working towards fully achieving it. Nevertheless, the European Commission found it necessary to enact a new *E-Health Action Plan* in recognition of evolving market and behavioural trends since 2004. Now, more than ever, people are monitoring their health and well-being online or through devices such as smartphones. The new *Action Plan* 2012–2020 reflects this shift and aims to enhance user confidence in digital tools and apps while ensuring that the market conditions encourage continued innovation (European Commission 2012a: 2).

The Commission issued in 2012 the *Commission Staff Working Paper* on the applicability of the existing EU legal framework to telemedicine services (European Commission 2012b). Due to its diverse nature and unique characteristics, cross-border telemedicine falls within the scope of EU legal instruments. In the past, there was no specific EU legislation governing cross-border telemedicine. The objective of the *Staff Working Paper*, therefore, was to enhance legal clarity for all actors involved in the provision of telemedicine services (European Commission 2012b: 4). The document clarifies the EU legislation's applicability to issues such as reimbursement, liability, licensing of healthcare professionals, and data protection when providing telemedicine across borders.

Since 2013, the Commission has engaged in 'discussions on legal issues affecting eHealth, within the eHealth Network and other fora, such as the European Innovation Partnership on Active and Healthy Ageing (EIP AHA), as well as cross-sectoral legal work linking eHealth to other ICT-led innovation, with the first conclusions foreseen in 2013–2014' (European Commission 2012c: 8). In order to bring legal clarity for health and well-being apps, a European Commission green paper on mobile health and well-being apps is scheduled to come into effect in 2014. The Commission will also initiate discussions among Member States on reimbursement schemes for e-health services based on effectiveness and efficiency criteria. The Commission will also launch a study under the upcoming Health Program 2014–2020 to examine member states laws' on electronic health records and make recommendations to the eHealth Network on legal aspects of interoperability.

15.3 Treaty on the Functioning of the European Union

Besides the policy documents of the Commission, it is important to mention the legal documents that apply to e-health. The *Treaty on the Functioning of the European Union* 2010 (TFEU) contains a number of important principles in addressing e-health, namely the right to the protection of

⁵ E-health also represented an important aspect of the Digital Agenda for Europe (European Commission 2010).

⁶ An overview of e-health projects 2007–2013 is available online (eHealthNews 2006).

personal data (article 16), the free movement of goods (articles 34–36), the freedom to provide services within the EU (article 56),⁷ the competition rules (articles 101, 102 and 106) and the subsidiary competence of the EU in the health field (article 168).

The European Union seeks to create a single internal market characterised by open competition. Therefore a system of competition law was developed to prevent the disruption of free competition or to neutralise any such disruption (Prosser 2010; Lear *et al.* 2010). Community competition rules prohibit undertakings in anti-competitive activities, such as agreements to set prices or abuse of a dominant position (TFEU, articles 101–102). Article 101 of the TFEU prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices that may affect trade between member states, and that have as their object or effect the prevention, restriction or distortion of competition within the common market. Article 102 of the TFEU prohibits abuse of a dominant position by one or more undertakings. Article 106 of the TFEU is also important to healthcare, as it permits partial exemption from the competition rules for some undertakings. This article states that undertakings entrusted with the operation of services of general economic interest shall be subject to the rules contained in the TFEU. In particular, the article outlines rules on competition, insofar as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Community.

The rules of European competition law, for example, can apply to electronic networks. Independent healthcare practitioners may have a common computer server to exchange patient information. Such collaboration does not come under the prohibition of cartels if some conditions are fulfilled. Firstly, the electronic system in principle may not be used for the exchange of competitively sensitive information about patients, prices, turnover, etc. (Beurden 2003: 106–8), as the exchange of such information can eliminate competitive undertakings. Secondly, an information network must be open. If the participants of a network benefit from this network, and others who do not participate cannot achieve these economic benefits, it will be difficult for healthcare practitioners to establish themselves in the market (Dutch National Competition Authority 2010: 98).

Moreover, article 168 of the TFEU defines the role of the European Union as complementing national policies, setting out procedures by which the European Union institutions act in the health field and delineating the types of measures that may be enacted. This article ensures a high level of human health protection in the definition and implementation of all EU policies and activities (WHO 2012a: 25). However, the TFEU also requires that healthcare service decisions be made at the national or local level (the legal principle of subsidiarity). The EU thus has only a limited legal competency on health matters. It can adopt measures that complement national initiatives or incentive measures designed to protect and improve human health, in particular to combat the major cross-border health scourges (WHO 2012a: 25).

15.4 Directives and regulations applicable to e-health

There is a wide range of directives and regulations applicable to healthcare actors who use e-health strategies. This section lists pertinent documents and discusses issues in e-health implementation.

⁷ 'Telemedicine is a service and as such falls under the provisions of the TFEU (i.e. its Article 56). The European Court of Justice has, on several occasions, stated that health services fall within the scope of the freedom to provide services (Article 56 TFEU) and neither the special nature of health services nor the way in which they are organized or financed removes them from the ambit of this fundamental freedom' (European Commission 2012b: 7).

15.4.1 Data Protection Directive

Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data 1995 (*Data Protection Directive*) is the EU-level legislation on privacy, to which all member states in the EU must comply, and guides the processing and free movement of personal data. It outlines several mandatory compliance principles for e-health actors that process personal data concerning health. These principles apply to national healthcare systems or other e-health actors that create health grids, electronic national records or information systems that may be used for treatment, quality review or research purposes. In order to help member states interpret their duties under the *Directive*, representatives of the national data protection authorities established a Working Party, formally known as the Article 29 Data Protection Working Party (WHO 2012a: 25). Its function is to advise the European Commission on the implementation of the *Data Protection Directive* in the member states and to report on the processing of personal data relating to health in electronic health records (EHR) (Article 29 Data Protection Working Party 2007).

The *Data Protection Directive* applies to the processing of personal data wholly or partly by automatic means, and to the processing of personal data by other means, which form part of a filing system or are intended to form part of a filing system⁸ (*Data Protection Directive*, article 3). Generally, article 8 of the *Data Protection Directive* prohibits the processing of personal data concerning health. However, this prohibition does not apply where the processing of health data is required.⁹ For example, the processing of health data for the purposes of preventive medicine, diagnosis, the provision of care or treatment or the management of healthcare services is permitted where such data are processed by a health professional subject to national law or rules established by national competent bodies obliging professional confidentiality, or by another person also subject to an equivalent confidentiality obligation.

According to the *Data Protection Directive*, personal data used in e-health projects, for example, must be processed fairly and lawfully. Furthermore, data must only be collected and processed for specified, explicit and legitimate purposes. The data must be adequate, relevant and not excessive in relation to the purposes for which they are collected. Furthermore, the data must reveal the identity of subjects for no longer than is necessary, and only for the purposes for which the data was collected or is required for further processing. Data subjects must also be informed about the processing of their personal data (*Data Protection Directive*, article 6).

Data transfer between member states for e-health projects ensures adequate protection of the data during transfer to the second member state, since it is responsible for providing a similar level of protection. The *Data Protection Directive* stipulates that the transfer of data undergoing processing or intended for processing after transfer to a third country may take place only if the third country ensures an adequate level of protection (*Data Protection Directive*, article 25.1; Rowe 2003). Adequacy is assessed in light of all the circumstances surrounding a data transfer operation or set of data transfer operations. Particular consideration is given to the nature of the data, the

8 A filing system is 'any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralized or dispersed on a functional or geographical basis' (*Data Protection Directive*, article 2(c)).

9 The European Court of Justice stated in *Lindqvist* (2003), Case C-101/01 ECR I-12971, that the act of referring, on an Internet page, to various persons and identifying them by name or by other means constitutes 'the processing of personal data wholly or partly by automatic means' within the meaning of article 3(1) of the *Data Protection Directive*. Such processing of personal data in the exercise of charitable or religious activity is not covered by any of the exceptions in article 6(2). In this case, the fact that it was mentioned on the Internet that an individual had injured his/her foot and was on half-time leave on medical grounds constitutes personal data concerning health within the meaning of article 8(1) of the *Data Protection Directive*.

purpose and duration of the proposed processing operation(s), the country of origin and country of final destination, the rules of law (both general and sectoral) in force in the third country, and the professional rules and security measures in place (*Data Protection Directive*, article 25.2).¹⁰

The frequency of data transfers between the EU and the United States, and uncertainty surrounding the ‘adequacy’ standard, prompted the United States Department of Commerce to issue the ‘Safe Harbor Principles’ under its statutory authority to foster, promote and develop international commerce. The European Commission has recognised these Safe Harbor Principles in *Decision 2000/520/EC* of 26 July 2000 (European Commission 2000).

A replacement of the *Data Protection Directive* is envisioned. The Proposal of the European Commission for a *General Data Protection Regulation* was submitted on 25 January 2012 (European Commission 2012g).

15.4.2 E-commerce Directive

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market 2000, the so-called *E-commerce Directive*, discusses certain legal aspects of information society services in the internal market. These services are defined as any service normally provided for remuneration, at a distance and by electronic means,¹¹ for the processing (including digital compression) and storage of data, and at the request of a service recipient (*Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services 1998*, article 1.2).¹² ‘At a distance’ denotes service provision without the simultaneous presence of both parties (Van Eecke 2001: 369). Since the economic activities of an information society service can consist of services giving rise to online contracting, several e-health applications can be the subject of an information society service. The *E-commerce Directive* may apply to online medicine purchases, as well as to services that transmit or provide access to information via a communication network. The *E-commerce Directive* may also apply to physicians who pay a fee to access a file using electronic research registers, who use a website to promote their activities or for sending medical information among physicians against remuneration (Van Eecke 2001: 375).

The *E-commerce Directive* obliges e-health actors who act as an information society service to provide the recipients of the service and competent authorities with direct and easy access to at least the following information: their name; the geographic address at which they are established; their details, including an electronic mail address; where their activity is subject to an authorisation scheme; the particulars of the relevant supervisory authority; as concerns the regulated professions, any professional body or similar institution with which they are registered; professional title and member state where it has been granted; a reference to the applicable professional rules in the member state of establishment and the means to access them (*E-commerce Directive*, article 5). According to the *E-commerce Directive*, member states must ensure that e-health actors

¹⁰ For exceptions to article 25 of the *Data Protection Directive*, see articles 26.1 and 26.2 of the *Directive*; see also Andoulsi *et al.*’s ‘Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids’ (2008: 21). The *Data Protection Directive* also states that member states may authorise a transfer or a set of transfers of personal data to a third country that does not ensure an adequate level of protection of personal data, where the controller adduces adequate safeguards through appropriate contractual clauses between the sender and the recipient of the personal data (*Data Protection Directive*, article 26.2). In this context, the European Commission has proposed standard contractual clauses that ensure an adequate level of protection of transferred personal data (for example, the storage of pharmacogenetic data or research data concerning health).

¹¹ Communication by phone, fax or global system for mobile communications does not fall under the *Directive*.

¹² The recipient can be a patient or a physician asking for an opinion.

indicate any relevant codes of conduct to which they subscribe and indicate how those codes can be consulted electronically (*E-commerce Directive*, article 10.2).¹³

Member states must guarantee that the take-up and pursuit of the activity of an information society service provider may not be made subject to prior authorisation or any other requirement having equivalent effect (*E-commerce Directive*, article 4.1). Article 4.1 of the *Directive* shall be without prejudice to authorisation schemes that are not specifically and exclusively targeted at information society services, or that are covered by *Directive 97/13/EC on a common framework for general authorizations and individual licences in the field of telecommunications services 1997*. This important principle articulated in article 4 of the *E-commerce Directive* is a major challenge for national e-health networks or telemedicine projects for which the competent public authorities want to provide reimbursement under certain conditions.

15.4.3 Medical Device Directives

E-health often requires medical software and/or implanted devices used to diagnose or treat patients. Therefore *Directive 90/385/EEC regarding active implantable medical devices 1990*, *Directive 93/42/EEC regarding medical devices 1993* and *Directive 98/79/EEC regarding in vitro diagnostic medical devices 1998* (*Medical Device Directives*) are also important for e-health projects. The *Medical Device Directives* harmonise the rules pertaining to the free circulation of medical devices in the EU. Products that fall within their scope must meet all essential safety and administrative requirements, and must bear an EC-conformity mark to show that they comply with the *Medical Device Directives*. Such products may then be sold throughout the European Economic Area without, in principle, being the subject of additional national legislation. The *Medical Device Directives* define a medical device as:

any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specially for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used for human beings for, among other things, the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap and the control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

(*Medical Device Directives*, article 1.2(a))

Software used in an e-health project for general purposes is not a medical device. However, software intended by the manufacturer to be used for one or more of the medical purposes established in the definition of a medical device is a medical device.

The manufacturer must design and manufacture medical devices in such a way that some essential requirements are met, such as taking into account the generally acknowledged state of the art and to eliminate or reduce risks as much as possible. Devices that are in accordance with national provisions that have transposed the existing European harmonised standards will be presumed by EU member states to be compliant with the essential requirements laid down by the Directive.

¹³ In order to facilitate the free provision of services in general, there are specific rules aimed at the abolition of obstacles to the free movement of persons and services, which extend the possibility of pursuing professional activities under the original professional title (European Union 2005; Peeters 2010).

In the context of the *Medical Device Directives*, manufacturers are obliged to place on the market or to put into service only medical devices that do not compromise the safety and health of patients, users and other persons, when properly installed, maintained and used in accordance with their intended purpose. In designing and producing state-of-the-art medical devices, the manufacturer must meet essential requirements that ensure patient safety and reduce risks. Devices that are in accordance with national provisions that have transposed the existing European harmonised standards will be presumed by EU member states to be compliant with the essential requirements laid down by the Directive (*Medical Device Directives*, article 5). Devices other than those custom-made or intended for clinical investigation must bear an EC-conformity mark when placed on the market. Clinical evaluation is also required and it remains to be seen how medical software vendors will fulfil this obligation.

Clinical evaluation is needed for every medical device. This clinical evaluation can be done in different ways. For instance, it may be based on the relevant scientific literature, by conducting a clinical investigation, or by combining both methods (*Directive 2007/47/EC*, Annex II, 10(a)). For active implantable devices and Class III devices,¹⁴ there must always be a clinical investigation (*Directive 2007/47/EC*, Annex II, 10(b)). Therefore clinical investigation will be necessary for medical implantable software or software listed under Class III.

The European Commission has since enacted two proposals to revise the *Medical Device Directives* (European Commission 2012d; European Commission 2012e). These proposed ‘new rules aim to ensure that patients, consumers and healthcare professionals can reap the benefits of safe, effective and innovative medical devices’ (European Commission 2012f: 1).

15.4.4 Directive on the Recognition of Professional Qualifications

Directive 2005/36/EC on the recognition of professional qualifications 2005 (including for medical doctors and a number of medical specialties) is recognised universally among EU member states. The aims of this *Directive* are to ensure that the European Union member states enact uniform, transparent and non-discriminatory rules recognising professional qualifications and experience, so as to allow professionals to work temporarily or permanently throughout the Union. However, this *Directive* will not apply in the case of (cross-border) telemedicine since the health professional and the patient are not simultaneously present. Article 5.2 of this *Directive* states that Title II (dedicated to the free provision of services) shall only apply where the service provider moves to the territory of the host member state to pursue his or her profession on a temporary and occasional basis. In the case of telemedicine, the health professional is not physically moving to the territory of another member state, only the ‘service’ itself moves. This *Directive* intends to recognise healthcare qualifications across EU borders. It is only applicable where the service provider actually moves to the territory of a host member state and thus does not apply to all e-health services.

15.4.5 Patients’ Rights Directive

E-health is covered in the scope of *Directive 2011/24/EU on the application of patients’ rights in cross border healthcare* 2011 (*Patients’ Rights Directive*).¹⁵ Cross-border healthcare services, including

¹⁴ Medical devices are divided into classes. For the classification rules, see *Directive 93/42/EC regarding medical devices* 1993 (European Union 1993).

¹⁵ This *Directive* contains two express references to telemedicine (European Commission 2012b: 7); see articles 3(d) and 7(7)) and its scope covers ‘the provision of health care to patients, regardless of how it is organized, delivered or financed’ (article 1(2)).

e-health, must be provided in line with the standards and guidelines on quality and safety in the member state of treatment (for e-health: the one of the service provider). According to article 3(d), 'Member State of treatment' refers to the member state on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is provided where the healthcare practitioner is established.

Article 14 of the *Patients' Rights Directive* establishes a voluntary network of national authorities knowledgeable in the area of e-health. The eHealth network is charged with drafting guidelines that enhance interoperability between electronic health systems, facilitate continuity of care and safeguard access to safe and quality healthcare.

15.4.6 Other directives and regulations

Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector 2002 (Directive on privacy and electronic communications) is also relevant. It contains specific requirements for providing publicly available communications services electronically, through secure and confidential networks (European Commission 2012b: 16).

Also pertinent is *Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services 1998 (Transparency Directive)*. Member states wishing to adopt regulation on telemedicine as an information society service must notify the Commission and other member states before adoption (European Commission 2012b: 11).

E-health business may also involve contractual agreements. These contracts describe various obligations and, often, special clauses concerning relevant parties. A contract related to e-health between professionals and consumers (for example, a contract between a patient and a tele-expert, or a contract between a patient and a pharmacist regarding the delivery of medicinal products) may be classified as a contract at a distance. *Directive 97/7/EC on the protection of consumers in respect of distance contracts 1997 (Directive on Distance Contracting)* will apply to any contract concerning goods or services concluded between a supplier and a consumer under an organised distance sales or service-provision scheme run by the supplier, who, for the purpose of the contract, makes exclusive use of one or more means of distance communication up to and including the moment at which the contract is concluded (*Directive on Distance Contracting*, article 2.1). Prior to the conclusion of any distance contract, the consumer shall be provided with sufficient information regarding the supplier's identity, the nature and cost of the services, arrangements for payment, delivery or performance, and the right to withdraw. Consumers must receive verifiable confirmation of the information stipulated in the contract in a timely fashion, unless the information has already been given, with the same provisos, prior to conclusion of the contract. For any distance contract, consumers will have a period of at least seven working days in which to withdraw without providing reason and without penalty.

E-health projects also often require electronic signatures. Electronic signatures are to be treated equal to handwritten signatures in the EU. An electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication (article 2.1 *Directive 1993/93/EC on a Community framework for electronic signatures*). Article 3.7 of *Directive 1999/93/EC* states that member states may use electronic signatures in the public sector upon meeting additional requirements. However, such requirements shall be objective, transparent, proportionate and non-discriminatory, and relate only to the application at hand. Such requirements may not constitute an obstacle to cross-border services for citizens (*Directive 1999/93/EC*, article 3.7).

A number of pieces of EU legislation regarding e-health projects should be considered, namely rules concerning the competent judge and the applicable law, i.e. *Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters*, *Regulation 593/2008 on the law applicable to non-contractual obligations (Rome I)* and *Regulation 864/2007 applicable to non-contractual obligations in tort law (Rome II)*.

15.5 Current and emerging issues pertinent to e-health¹⁶

Despite legal and regulatory issues related to e-health at the international and/or EU level, it is our opinion that a more detailed legal framework is needed to allow the use of this activity in healthcare systems. This framework should consider all interests at stake, such as data protection, public health, quality of care, cost-effectiveness, etc. It requires more legal provisions (for example, rules are needed on liability and reimbursement matters) and greater attention to new technical developments (for example, the lack of clarity for health and well-being mobile applications, the role of data centres) (European Commission 2012c; Stroetmann 2012).

15.5.1 Towards more similar liability rules

Certain e-health domains, like telemonitoring, raise several and often complex liability issues. For example, who will be liable for errors during a monitoring session (the physician or healthcare professional, the healthcare institution, the manufacturer of the device (liability for defective products), the telephone/Internet company, the call centre)? Which member state supervises physicians in cross-border healthcare? Which legislation is applicable in case of cross-border healthcare? Liability can stem from professional conduct or a defective product. Moreover, depending on whether a contractual relationship exists between the damaged person and the person responsible for the damage, a case of contractual liability or tort liability could arise (European Commission 2012b: 19).

To date, there is no international consensus document regulating liability in cases of telemonitoring. Nevertheless, the EU general liability rules (*Rome I* and *Rome II* – see above) are also applicable in healthcare. *Directive 85/373/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products 1985 (Product Liability Directive)* and the *Patients' Rights Directive* may be applicable in case of damage caused by telemonitoring.

It is, however, obvious that different medical liability legislation in the EU member states (including legislation concerning compensation for damages caused by medical acts) may hinder the application of telemonitoring. Patients seeking cross-border healthcare services may not necessarily always remain under the scope of legal protection offered by their own legal system. Therefore the EU and other international organizations should take heed in liability issues.

Countries that enact legislation concerning compensation for damages caused by medical acts should ideally not exclude damage that is caused by medical acts carried out in another member state. The *Patients' Rights Directive* declares EU member states must ensure there are mechanisms for patients to seek redress and compensation if they suffer harm. If in a telemonitoring project the physician does not reside in the member state where treatment is taking place and the patient suffers harm due to treatment/monitoring at a distance (from another member state), the local no-fault legislation of the member state of residence of the patient should ideally apply to the patient. It would be good for promoting (internationally) e-health projects if

¹⁶ This section is based on 'Legal aspects of personal health monitoring' (Callens 2013: 57–62).

no-fault legislation of a member state (or specific legislation with a compensation system for damage caused by medical activities) should not be limited to harm caused in the patient's state of residence. In that case only the local e-health projects that cause damage could be covered by specific compensation rules.

15.5.2 Transparency

If the telemonitoring device is to function as an alert device, this should be clearly communicated to patients. Patients should be informed what actions they must take and what actions to expect from the treating physician. The patient must also be informed about the information flows and the categories of persons who might have access to their data. Patients should be allowed access to login files. Authorised healthcare professionals with access to electronic patient files should be informed of the possibility that patients or competent persons of the health institute may verify access. Patients must also be informed about the device and the treatment plan. Patients (or their representative) must consent to the treatment and the (further) processing of health data for purposes other than treatment.

The globalisation of healthcare actors requires greater harmonisation in health data processing, particularly as data exchange between international or European e-health actors will not be limited to the treatment of patients during monitoring sessions and may also be processed for evaluation, research or statistical purposes. Currently, harmonised rules on further processing are lacking. Several member states of the EU have formulated strict rules for the processing of medical data for research purposes while others are more flexible. Article 8 of the *Data Protection Directive* leaves too much room for different legislation among member states. Legislative differences are detrimental to the establishment of an internal market, where international quality review projects, epidemiological studies, clinical trials, etc. are emerging, and especially in the context of globalised healthcare.

In other words, remedying the current weakness of the *Data Protection Directive* requires more European action. Adopting a proposal for the new *General Data Protection Regulation* (see above) is one example of this action. The proposal contains innovative ideas, such as the 'the right to be forgotten' in the online environment or the right to delete all personal data that are publicly available. One other key feature includes mandating *explicit* patient consent for data processing rather than assumed consent.

15.5.3 Challenges for healthcare practitioners and hospitals

The role of different health professionals may change in view of developing telemonitoring. We believe that nurses and medical assistants may play a growing role. Surveillance of monitoring systems also implies that there will be a shift from inpatient to outpatient treatment. The role of the hospital will change, eventually monitoring outpatients not physically present or admitted to the hospital. Because of the cross-border effect of telemonitoring, some hospitals may also become international, or at least for the moment European-wide, referral centres. The use of monitoring devices will also lead to changes in the way physicians and hospitals function. Physicians, other healthcare professionals and hospitals will need to be on standby for their patients in case of an emergency. This requires organising a guard duty, probably with many other healthcare professionals in light of the increasing physician shortage in several member states. In implementing telemonitoring services, the guard duty will need to consider the influx of patients to follow patients who are not physically present in the hospital. Many of these patients may reside in regions other than where the treating hospital is located. E-health, and

in particular telemonitoring, will simplify cross-border healthcare and reference centres will treat more patients (from several countries). Thus telemonitoring urges healthcare personnel and hospitals to work collaboratively beyond their national boundaries.

15.5.4 Towards the reimbursement of e-health services

In the EU member states, it is often still required that the patient and health professional are both present in order for a medical act to be legally recognised and reimbursed. This condition is not fulfilled in many telemonitoring projects whose value lies in the free movement of services without an in-person consultation. The question then becomes whether or not the condition still legitimises withholding reimbursements for telemonitoring projects. Not surprisingly, new monitoring projects often end due to a lack of financing structure. Although reimbursement is an issue to be treated by the individual member states, clear EU-level criteria for reimbursement, much like *Directive 89/105/EC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems* 1988 outlined for medicinal products, might be useful.

The rules of reimbursement for cross-border care as provided in the *Patients' Rights Directive* (2011) are of import to telemedicine. The member state of affiliation must guarantee reimbursement of the costs an insured person incurs upon receiving cross-border healthcare if it is among the benefits the insured person is entitled to in the member state of affiliation.

15.5.5 Relationship between patient and industry: challenges concerning publicity, promotion and competition

The role of the medical devices and the pharmaceutical industry will change if healthcare settings increasingly apply telemonitoring projects, web portals designed to share information between patient and healthcare professional, mobile health apps, etc. Delegates and employees from the medical device industry may be in direct contact with the patients when, for example, implanting a monitoring device, to give information about its function or about the health status of the patient. The data may be gathered in a data centre that will send the necessary information a treating physician needs. In the past, the industry's only contacts were with health professionals and distributors; there was, in principle, no direct contact between the industry and patients. Telemonitoring projects are changing this dynamic, especially if the device manufacturer owns the data centres or if the industry installs and/or follows up with the device.

Specific rules at the European level will be needed to regulate the relation between the healthcare industry and the patient in the monitoring sector, in order to avoid illegal promotion and/or advertising, illegal overconsumption or unfair competition. If devices, or even data centres, are made available to hospitals or health professionals free of charge, this may be considered an illegal advantage for the healthcare professional/facility. Administering free products and/or services may also violate competition rules. In rethinking the role/function of the industry, it is clear that it will become more involved in the treatment and follow-up of patients with a device or web portal. More and more custom-made devices adapted to the specific needs of the patients will be developed and used. Patients will need to become more familiar with how the device works and what to do when it malfunctions. However, healthcare professionals will no longer be the only providers of this information, nor will they deliver the devices. Patients will obtain devices from the manufacturer/supplier and not necessarily from the (hospital) pharmacist. If retailers, consumer product companies and others can deliver the devices to patients, these companies may want to inform patients directly and assist them in using the device. It will be a

challenge for these companies to ensure there is a clear distinction in practice between providing information and advertising at the time of initial contact between the company and the patient.

Telemonitoring also allows data processing for several purposes. The data centre may gather information related to the implanted/used device in monitoring projects and/or the patient which may be processed by the industry prior to reaching the health professional. The question is whether the companies who deliver implants can own the data centre, perhaps making it more difficult for hospitals to work with several types of implants due to competition law, or whether new independent healthcare players should run them.

Until now, there was no extensive European legislation concerning the advertising and distribution of medical devices used in telemonitoring projects. If the industry begins to play a more active role in direct patient use of monitoring devices, clearer rules are needed at the EU-level. Namely, legislation will serve to distinguish between information provided by the industry and advertising, to address issues of promotion and cost of data centres or health personnel involved in telemonitoring projects, to allow patients to choose who assists them in using the device and to monitor the use of data processing at data centres.

15.6 Conclusion

Many healthcare players (such as national health insurers, hospitals, laboratories, etc.) are now international healthcare actors and may feel the need to communicate health data between member states for treatment and other purposes. Patients communicate with healthcare professionals from other countries through telemonitoring projects without having to go abroad. Thus a clear legal framework for e-health is needed. Until now, data processing, distance contracting and medical device marketing have dominated discussions surrounding e-health strategies. However, despite rules and policy attention, several e-health issues require a more critical legal gaze. Clear criteria on the reimbursement of e-health activities, similar rules concerning (no-fault) liability and greater care in ensuring transparency in relationships between patients and the industry are needed.

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